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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/13/2006

Stephen Martone

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PRTSI

P.O. Box 16446

Arlington, VA 22215

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3779

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DELIVERY MODE

12/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,927	Applicant(s) MARTONE ET AL.	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3779	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,48-50,73-76,79-90,92 and 94-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,48-50,73-76,79-90,92 and 94-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29, 2010 has been entered.

Notice of Amendment

In response to the amendment filed on November 29, 2010, amended claims 1; canceled claims 44-47, 77-78, 91 and 93; and new claims 92-93 are acknowledged. The following new grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43, 48, 73-77, 79, 81-84, 86-89, 92 and 94-97 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No 5,503,616 to Jones.

In regard to claim 43, Jones discloses a sheath assembly for a probe, comprising: an internal sheath 30 and/or 50 configured to isolate a probe from body fluids; and an external sheath 20 surrounding the internal sheath (see Figs. 3-6), the

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external sheath configured to define a channel for passing fluids, tools or working tubes and the internal and external sheaths being connected to each other (see Col. 4, Lines 37-57), wherein the external sheath and the internal sheath are not coupled along their length (see Col. 4, Lines 12-15), and wherein the internal sheath is not affected when tools or working tubes are passed through the channel (see Col. 5, Lines 1-22).

In regard to claim 48, Jones discloses a sheath assembly for a probe, wherein the internal and external sheaths are connected substantially only at a plurality of circumferential points at a distal end of the external sheath (see Col. 4, Lines 12-15). It is inherent that if more than one access channel is provided (see Col. 5, lines 62-67), then the internal and external sheaths would be connected at a plurality of circumferential points.

In regard to claim 49, Jones discloses a sheath assembly for a probe wherein the internal and external sheaths coextend at their distal ends, such that their distal ends extend to a same point (Figs. 3-6).

In regard to claim 73, Jones discloses a sheath assembly for a probe wherein at least one channel 64 is defined between the external sheath and the internal sheath along at least a portion of the sheath assembly (Figs. 6 and 8 and Col. 5, Lines 40-65).

In regard to claim 74, Jones discloses a sheath assembly for a probe wherein at least one channel is open at the distal end of the sheaths (Col. 4, Lines 38-56).

In regard to claim 75, Jones discloses a sheath assembly for a probe wherein the channel does not surround the entire internal sheath (Figs. 3-6).

In regard to claim 76, Jones discloses a sheath assembly for a probe wherein there are two channels (see Col. 5, Lines 62-67).

In regard to claim 79, Jones discloses a sheath assembly for a probe wherein the external sheath and the internal sheath are connected to a proximal connector (see Fig. 8 and Col. 5, Lines 40-60). It is inherent that the internal sheath would also be connected to a proximal connector in the same fashion that the external sheath is connected to a proximal connector.

In regard to claim 81, Jones discloses a sheath assembly for a probe wherein the external sheath is sealed at its distal end (see Figs. 3-6 and Col. 4, Lines 12-15).

In regard to claim 82, Jones discloses a sheath assembly for a probe wherein the internal sheath comprises an imaging window at its distal end (see Col. 4, Lines 63-67).

In regard to claims 83-84 and 86, Jones discloses a sheath assembly for a probe wherein the internal and external sheaths are foldable, bendable and/or stretchable (see Col. 3, Lines 55-67 and Col. 5, Lines 1-11). The sheaths are fully capable of being bent, folded or stretched.

In regard to claim 87, Jones discloses a sheath assembly for a probe wherein a sheath assembly wherein the internal and external sheaths have *substantially* the same thickness (see Figs. 2-6).

In regard to claim 88, Jones discloses a sheath assembly for a probe wherein the internal and external sheaths are formed from the same material (see Col. 3, Lines 55-67, Col. 5, Lines 1-11 and Col. 5, Lines 30-32).

In regard to claim 89, Jones discloses a sheath assembly for a probe wherein, a rigid pipe section 70 is located at at the proximal end of the internal sheath (see Col. 5, Lines 37-41).

In regard to claim 92, Jones discloses a sheath assembly for a probe wherein, wherein the external sheath extends over at least 50% of the internal sheath (See Col. 3, Line 67 – Col. 4, Line 1).

In regard to claim 94, Jones discloses a sheath assembly for a probe wherein the internal sheath is bendable, configured to bend longitudinally around corners while the sheath assembly is inserted into a patient (see Col. 3, Line 55 – Col. 4, Line 36 and Col. 5, Lines 1-11).

In regard to claim 95, Jones discloses a sheath assembly for a probe wherein the external sheath is folded (i.e. collapsed) during insertion into the body (See Figs. 1-3 and 5).

In regard to claim 96, Jones discloses a sheath assembly for a probe wherein the external sheath and the internal sheath are coupled at their distal ends only (see Col. 4, Lines 12-15).

In regard to claim 97, Jones discloses a sheath assembly for a probe wherein the channel imparts an asymmetrical force on the internal sheath when tools or working tubes are passed through the channel (see Figs 2-6). Because the external sheath is attached along one side of the internal sheath, an asymmetrical force inherently is applied to the internal sheath upon insertion of a tool therethrough.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 5,503,616 to Jones in view of U.S. Patent No 6,740,030 to Martone et al.

In regard to claim 50, Jones discloses a sheath assembly for a probe (see rejection above) but is silent with respect to wherein the internal sheath extends beyond the distal end of the external sheath. Martone et al. teach of an analogous endoscopic sheath wherein the endoscope assembly 400 includes a sheath 410 having a tubular body portion 412, a proximal fitting 442 engageable with the engagement portion 44 of the endoscope 20 (FIG. 1), and an end cap 413 attached to a distal end of the body portion 412. The end cap 413 includes a substantially transparent distal end 415 to enable viewing through the viewing lens 31 of the endoscope 20. The endoscope assembly 400 further includes a working channel 420 having a spiral cut 424 therethrough, and an enlarged end portion 425 proximate the working end 26 of the insertion tube 22. The enlarged end portion 425 may be sized to receive an operating end 451 of a medical device 450. The working channel 420 further includes an open, proximal end 448 near the endoscope 20. Because the enlarged end portion 425 at least partially surrounds and covers the operating end 451 in the non-operating position 460, the enlarged end portion 425 may ease the task of inserting (and removing) the

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endoscope assembly 400 into the patient's body cavity, thereby reducing the trauma to the surrounding tissues and ultimately the discomfort experienced by the patient. The enlarged end portion 425 may also ensure that the operating end 451 does not become occluded with unwanted or undesirable foreign matter during insertion of the endoscope assembly 400 which might inhibit the physician's ability to perform the desired medical procedure (see Figs. 11-12). Thus, for such states reasons, it would have been obvious to one skilled in the art at the time the invention was made to provide an internal sheath which extends beyond the external sheath in the apparatus of Jones as taught by Martone et al.

Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 5,503,616 to Jones in view of U.S. Patent No 7,431,694 to Stefanchik et al.

In regard to claims 80, Jones discloses a sheath assembly for a probe (see rejection above) but is silent with respect to the external sheath is formed with an internal notch capable of receiving a dovetail of a working tube. Stefanchik et al. teach of an analogous endoscopic sheath comprising an attachment flange 25 for connecting rail 30 to endoscope 100. A sheath 80 surrounds endoscope 100 and rail 30. Rail 30 can be joined to an inner surface of sheath 80. Such an embodiment allows passage of mating member 40 and accessory 50 within sheath 80, providing for atraumatic passage along the tissue surface (see Fig. 6). It would have been obvious to one skilled in the art at the time the invention was made to provide an internal notch capable of receiving a dovetail of a working tube in the apparatus of Jones to provide an

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alternate means for inserting a working tube to a target site within the body as taught by Stefanchik et al.

Claim 85 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 5,503,616 to Jones in view of U.S. Patent No 7,431,694 to Stefanchik et al.

In regard to claims 85 and 90, Jones discloses a sheath assembly for a probe (see rejection above) but is silent with respect to the external sheath being non-collapsible and non-elastic. Bacich et al. teach of an analogous endoscopic sheath wherein the external sheath is non-elastic (Col. 14, lines 25-29). Furthermore, Bacich discloses that the external sheath is non- self collapsible (Col. 14, lines 8-12). It would have been obvious to one skilled in the art at the time the invention was made to provide a non-collapsible external sheath in the apparatus of Jones to provide an alternate means allowing for easier and faster insertion of an instrument therethrough during a surgical procedure as taught by Stefanchik et al. and is well known in the art.

Response to Arguments

Applicant's arguments with respect to claims 43, 48-50, 73-76, 79-90, 92 and 94-97 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas J. Sweet can be reached on (571) 272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/
Primary Examiner, Art Unit 3779

12/13/10